



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2013-0292; FRL-11021-01-ORD]

Public Comment on the Cumulative Risk Assessment Guidelines for Planning and Problem Formulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a 60-day public comment period on the draft Cumulative Risk Assessment (CRA) Guidelines for Planning and Problem Formulation. The CRA Guidelines for Planning and Problem Formulation describe steps for the planning and problem formulation of CRAs and offer guidelines for when cumulative risk assessments could be appropriate. Planning defines both the process for conducting the risk assessment and its general scope, while problem formulation identifies major factors considered in a specific assessment to inform its technical approach. The draft CRA Guidelines for Planning and Problem Formulation are not final, and do not represent, and should not be construed to represent, Agency policy or views.

DATES: The 60-day public comment period begins [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] and ends [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to be considered by EPA.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-ORD-2013-0292, by any of the following methods:

- Federal eRulemaking Portal: <https://www.regulations.gov/> (our preferred method).

Follow the online instructions for submitting comments.

- Mail: U.S. Environmental Protection Agency, EPA Docket Center, [insert Program Office Name] Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- Hand Delivery or Courier: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this notice.

Comments received may be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the public comment process, see the **PUBLIC PARTICIPATION** heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202-566-1752; facsimile: 202-566-9744; or email: Docket_ORD@epa.gov. For technical information on the draft guidelines or information on the public comment period, contact Dr. Lawrence Martin, via email at: martin.lawrence@epa.gov; or via phone/voicemail at 202-308-5642.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Written Comments: Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2013-0292, at <https://www.regulations.gov> (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to EPA's docket at <https://www.regulations.gov> any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. If you are commenting on specific text in the document, please use the page and line number to identify the text to which you refer. General recommendations

or comments are best tied to a specific section in the text that comes closest to addressing the issue you are commenting upon. If no such section exists, then a recommendation for a new section heading is helpful. Please provide citations for any technical information and/or data used to support the information you provide. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system). Please visit <https://www.epa.gov/dockets/commenting-epa-dockets> for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

II. Background on the CRA Guidelines for Planning and Problem Formulation

The draft CRA Guidelines for Planning and Problem Formulation is available at <https://www.epa.gov/risk/guidelines-cumulative-risk-assessment-planning-and-problem-formulation> and in the public docket at <http://www.regulations.gov>, Docket ID No. EPA-HQ-ORD-2013-0292.

The CRA Guidelines for Planning and Problem Formulation focus on this first phase of a cumulative risk assessment. The document does not address other elements of the cumulative risk assessment process, including conducting an analysis, risk characterization, risk communication, or risk management. Public comments focused on the planning and problem formulation phase of a cumulative risk assessment would be most useful.

EPA undertook the development of methods for CRA beginning with the 1997 Guidance on Cumulative Risk Assessment, Part 1, Planning and Scoping. In 2003, EPA published *A Framework for Cumulative Risk Assessment*. EPA continued to advance CRA methods to support understanding and reducing risks to people in disproportionately impacted communities, in 2008 publishing *Concepts, Methods, and Data Sources for Cumulative Health Risk*

Assessment of Multiple Chemicals, Exposures and Effects. This draft CRA Guidelines for Planning and Problem Formulation build off the 2003 CRA Framework and updates the 1997 CRA Guidance. The draft CRA Guidelines for Planning and Problem Formulation provides methods by which stressors are identified and incorporated into problem formulation and a conceptual model. In June 2021, the draft CRA Guidelines for Planning and Problem Formulation received an independent contractor-led external panel peer review. Subsequent revision has produced the draft CRA Guidelines for Planning and Problem Formulation that is now released for public comment.

III. How Will Comments be Used?

Public comment received on the draft CRA Guidelines for Planning and Problem Formulation will be reviewed and considered to be incorporated into or modify text in the final revised draft of the Guidelines. The final draft Guidelines will then undergo internal EPA review and revision, and then be finalized for publication.

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